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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,785

10/03/2005

Marco Cattaruzza

DEBE:053US/10501498

1068

32425 7590 10/27/2009  
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EXAMINER

WOLLENBERGER, LOUIS V

ART UNIT

PAPER NUMBER

1635

MAIL DATE

DELIVERY MODE

10/27/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,785	<b>Applicant(s)</b> CATTARUZZA ET AL.	
	<b>Examiner</b> Louis Wollenberger	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 24 June 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Status of Application/Amendment/Claims*

Applicant's response filed 6/24/2009 has been considered. Rejections and/or objections not reiterated from the previous office action mailed 4/3/2009 are hereby withdrawn.

Applicant's amendment to the claims, filed 6/24/2009, is acknowledged. With entry of the amendment, Claims 1 and 2 are pending and under examination.

### *Non-Statutory Double Patenting—maintained*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 2 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 11-19 of copending Application No. 10/526430. Although the conflicting claims are not identical, they are not patentably distinct

from each other because conflicting application 10/526430 claims a pharmaceutical formulation comprising a nucleic acid and a nonsteroidal anti-inflammatory drug.

MPEP §804 provides that "...those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim.

35 USC §112, first paragraph, support for claims 11-19 of copending application 10/526430 finds that the "nucleic acid" required for the nucleic acid-containing pharmaceutical formulation of claims 11-19 may be any of the double stranded decoy oligonucleotides defined by the disclosure. An updated STIC-Biotech sequence search of instant SEQ ID NO:17 finds that the double stranded oligonucleotide decoys in 10/526430 corresponding to SEQ ID Nos. 1, 2, 5, 6, 13, 14, 17, 18, and 37 each comprise instant SEQ ID NO:17. See selected alignments below. In particular, the double stranded decoy referred to therein as comprising SEQ ID NO:17 is identical to the decoy claimed in instant application 10/527785.

Thus, given that the "nucleic acid" recited in claims 11-19 of 10/526430 may be any one of the decoy oligonucleotides disclosed in the 10/526430 specification, and given that the instantly claimed decoy is intended for pharmaceutical use to treat an inflammatory condition, such as arthritis, one of ordinary skill in the art would conclude the double stranded

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oligonucleotide decoy defined by instant claims 1 and 2 would have been anticipated by or obvious in view of the nucleic acid-containing pharmaceutical formulation defined by claims 11-19 in conflicting application 10/526430.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that on 9/18/2009 a notice of Allowance was mailed in 10/526430.

```
RESULT 3
US-10-526-430A-17
; Sequence 17, Application US/10526430A
; Publication No. US20060258601A1
; GENERAL INFORMATION:
; APPLICANT: HECKER, MARKUS
; APPLICANT: WAGNER, ADREAS H.
; TITLE OF INVENTION: Functional correction of the -786C/T-variance of the human eNOS-gene
; FILE REFERENCE: DEBE:052US
; CURRENT APPLICATION NUMBER: US/10/526,430A
; CURRENT FILING DATE: 2005-03-01
; PRIOR APPLICATION NUMBER: PCT/DE 03/02901
; PRIOR FILING DATE: 2003-09-12
; PRIOR APPLICATION NUMBER: DE 102 42 319
; PRIOR FILING DATE: 2002-09-12
; NUMBER OF SEQ ID NOS: 63
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 17
; LENGTH: 16
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Decoy-Oligonucleotide
US-10-526-430A-17
```

```
Query Match          100.0%; Score 16; DB 14; Length 16;
Best Local Similarity 100.0%; Pred. No. 9e+02;
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
```

```
Qy      1 TCCCTGGCCGGCTGAC 16
        |||||
Db      1 TCCCTGGCCGGCTGAC 16
```

```
RESULT 4
US-10-526-430A-18/c
; Sequence 18, Application US/10526430A
; Publication No. US20060258601A1
; GENERAL INFORMATION:
; APPLICANT: HECKER, MARKUS
; APPLICANT: WAGNER, ADREAS H.
; TITLE OF INVENTION: Functional correction of the -786C/T-variance of the human eNOS-gene
; FILE REFERENCE: DEBE:052US
; CURRENT APPLICATION NUMBER: US/10/526,430A
; CURRENT FILING DATE: 2005-03-01
; PRIOR APPLICATION NUMBER: PCT/DE 03/02901
; PRIOR FILING DATE: 2003-09-12
; PRIOR APPLICATION NUMBER: DE 102 42 319
; PRIOR FILING DATE: 2002-09-12
; NUMBER OF SEQ ID NOS: 63
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 18
; LENGTH: 16
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Decoy-Oligonucleotide
US-10-526-430A-18
```

```
Query Match          100.0%; Score 16; DB 14; Length 16;
Best Local Similarity 100.0%; Pred. No. 9e+02;
```

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```
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 TCCCTGGCCGGCTGAC 16
        |||
Db      16 TCCCTGGCCGGCTGAC 1
```

```
RESULT 8
US-10-526-430A-13
; Sequence 13, Application US/10526430A
; Publication No. US20060258601A1
; GENERAL INFORMATION:
; APPLICANT: HECKER, MARKUS
; APPLICANT: WAGNER, ADREAS H.
; TITLE OF INVENTION: Functional correction of the -786C/T-variance of the human eNOS-gene
; FILE REFERENCE: DEBE:052US
; CURRENT APPLICATION NUMBER: US/10/526,430A
; CURRENT FILING DATE: 2005-03-01
; PRIOR APPLICATION NUMBER: PCT/DE 03/02901
; PRIOR FILING DATE: 2003-09-12
; PRIOR APPLICATION NUMBER: DE 102 42 319
; PRIOR FILING DATE: 2002-09-12
; NUMBER OF SEQ ID NOS: 63
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 13
; LENGTH: 19
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Decoy-Oligonucleotide
US-10-526-430A-13
```

```
Query Match          100.0%; Score 16; DB 14; Length 19;
Best Local Similarity 100.0%; Pred. No. 8.6e+02;
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 TCCCTGGCCGGCTGAC 16
        |||
Db      4 TCCCTGGCCGGCTGAC 19
```

```
RESULT 9
US-10-526-430A-14/c
; Sequence 14, Application US/10526430A
; Publication No. US20060258601A1
; GENERAL INFORMATION:
; APPLICANT: HECKER, MARKUS
; APPLICANT: WAGNER, ADREAS H.
; TITLE OF INVENTION: Functional correction of the -786C/T-variance of the human eNOS-gene
; FILE REFERENCE: DEBE:052US
; CURRENT APPLICATION NUMBER: US/10/526,430A
; CURRENT FILING DATE: 2005-03-01
; PRIOR APPLICATION NUMBER: PCT/DE 03/02901
; PRIOR FILING DATE: 2003-09-12
; PRIOR APPLICATION NUMBER: DE 102 42 319
; PRIOR FILING DATE: 2002-09-12
; NUMBER OF SEQ ID NOS: 63
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 14
; LENGTH: 19
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: Decoy-Oligonucleotide
US-10-526-430A-14
```

```
Query Match          100.0%; Score 16; DB 14; Length 19;
Best Local Similarity 100.0%; Pred. No. 8.6e+02;
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy      1 TCCCTGGCCGGCTGAC 16
        |||
Db      16 TCCCTGGCCGGCTGAC 1
```

```
RESULT 10
US-10-526-430A-37/c
; Sequence 37, Application US/10526430A
; Publication No. US20060258601A1
; GENERAL INFORMATION:
; APPLICANT: HECKER, MARKUS
; APPLICANT: WAGNER, ADREAS H.
; TITLE OF INVENTION: Functional correction of the -786C/T-variance of the human eNOS-gene
```

```
; FILE REFERENCE: DEBE:052US
; CURRENT APPLICATION NUMBER: US/10/526,430A
; CURRENT FILING DATE: 2005-03-01
; PRIOR APPLICATION NUMBER: PCT/DE 03/02901
; PRIOR FILING DATE: 2003-09-12
; PRIOR APPLICATION NUMBER: DE 102 42 319
; PRIOR FILING DATE: 2002-09-12
; NUMBER OF SEQ ID NOS: 63
; SOFTWARE: PatentIn version 3.1
; SEQ ID NO 37
; LENGTH: 19
; TYPE: DNA
; ORGANISM: Artificial Sequence
; FEATURE:
; OTHER INFORMATION: DNA Oligonucleotide
US-10-526-430A-37
```

```
Query Match          100.0%; Score 16; DB 14; Length 19;
Best Local Similarity 100.0%; Pred. No. 8.6e+02;
Matches 16; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
```

```
Qy      1 TCCCTGGCCGGCTGAC 16
          |||||
Db      18 TCCCTGGCCGGCTGAC 3
```

### ***Response to Arguments***

In the instant case, the conflicting application, 10/526430, has been indicated by the Office as allowable. No terminal disclaimer was required in the conflicting application.

### ***Claim Rejections - 35 USC § 103—withdrawn***

The rejection of Claims 1 and 2 under 35 U.S.C. 103(a) as being unpatentable over Moskowitz (US 2002/0132234) in view of Dzau et al. et al. (WO 95/11687) and Morishita et al. (1997) *Nature Medicine* 3:894-899 is withdrawn in view of Applicant's amendments to the claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis Wollenberger whose telephone number is (571)272-8144. The examiner can normally be reached on M-F, 8 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on (571)272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Louis Wollenberger/  
Primary Examiner, Art Unit 1635  
October 20, 2009